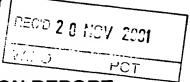


PCT



INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)



Applicant's or agent's file reference 53.70681/001				FOR FURTHER AC	CTION		ation of Transmittal of International Examination Report (Form PCT/IPEA/	/416)
Inte	mationa	al app	lication No.	International filing date (day/month/	year)	Priority date (day/month/year)	
PCT/EP00/07204			'204 	26/07/2000			27/07/1999	
	rnationa 1F2/46		ent Classification (IPC) or nat	tional classification and IP0	c 		•	
	olicant							
SU	ММІТ	ME	DICAL LIMITED et al.					
1.			ational preliminary exami smitted to the applicant a		prepared	by this Inte	rnational Preliminary Examining A	uthority
2.	This F	REPO	ORT consists of a total of	4 sheets, including this	s cover sh	eet.		
	b	een a	eport is also accompanied amended and are the bas sule 70.16 and Section 60	is for this report and/or	sheets co	ntaining re	n, claims and/or drawings which ha ctifications made before this Autho e PCT).	ave ority
	These	e ann	exes consist of a total of	sheets.				
3.	This r	eport	contains indications rela	ting to the following iten	ns:			
	1	×	Basis of the report					
	- 11		Priority					
	III		<u>-</u>	pinion with regard to no	velty, inve	entive step	and industrial applicability	
	IV			· ·	•			
	٧	⊠	Reasoned statement un citations and explanatio			ovelty, inve	entive step or industrial applicability	/;
	VI		Certain documents cite	d			•	
	VII	\boxtimes	Certain defects in the in	ternational application				
	VIII		Certain observations on	the international applic	cation			,
Date of submission of the demand					Date of co	ompletion of	this report	
09/02/2001					15.11.200)1		
		exami	g address of the international ining authority:		Authorize	d officer	(Joseph	SOES MICHAELD
	European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d					В	Rises SX March	
Fax: +49 89 2399 - 4465					Telephone	e No. +49 89	2399 2329	OHO. 1



International application No. PCT/EP00/07204

I. Basis of the report

the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally finance and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)): Description, pages:									
	1-8		as originally filed						
	Cla	ims, No.:							
	1-10	0	as originally filed						
	Dra	wings, sheets:							
	1/3-	3/3	as originally filed						
2.			uage, all the elements marked above were available or furnished to this Authority in the nternational application was filed, unless otherwise indicated under this item.						
	The	se elements were a	evailable or furnished to this Authority in the following language: , which is:						
		the language of a t	ranslation furnished for the purposes of the international search (under Rule 23.1(b)).						
		the language of pu	blication of the international application (under Rule 48.3(b)).						
		the language of a t 55.2 and/or 55.3).	ranslation furnished for the purposes of international preliminary examination (under Rule						
3.			leotide and/or amino acid sequence disclosed in the international application, the y examination was carried out on the basis of the sequence listing:						
		contained in the inf	ternational application in written form.						
		filed together with t	the international application in computer readable form.						
		furnished subseque	ently to this Authority in written form.						
		furnished subsequently to this Authority in computer readable form.							
		The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.							
		The statement that listing has been fur	the information recorded in computer readable form is identical to the written sequence rnished.						
4.	The	amendments have	resulted in the cancellation of:						
		the description,	pages:						
		the claims,	Nos.:						

1. With regard to the elements of the international application (Replacement sheets which have been furnished to

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP00/07204

		the drawings,	sheets:							
5.		This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):								
		(Any replacement she report.)	eet contail	ning such	h amendments must be referred to under item 1 and annexed to this					
6.	Add	litional observations, if	necessar	y:						
V.		soned statement und tions and explanation			vith regard to novelty, inventive step or industrial applicability; ch statement					
1.	Stat	ement								
	Nov	relty (N)	Yes: No:	Claims Claims						
	Inve	entive step (IS)	Yes: No:	Claims Claims	1-10					
	Indu	ustrial applicability (IA)	Yes: No:	Claims Claims	1-10					

VII. Certain defects in the international application

2. Citations and explanations see separate sheet

The following defects in the form or contents of the international application have been noted: see separate sheet

EXAMINATION REPORT - SEPARATE SHEET

An apparatus for containing and mixing orthopaedic cement comprising an outer housing defining a mixing chamber and an inner housing containing the cement prior to mixing, is generally known (see page 4, paragraphs 1 and 2 of the description).

The problem of the known device was that during transportation, the cement powder adheres to internal surface of the mixing chamber such that when a liquid monomer is introduced for mixing, some powder remains unmixed due to the monomer not wetting all of the wall surface. Thus, dry spots occur resulting in brittle cement which has adverse consequences.

This problem is solved by the features of claim 1 that the inner housing is removable from the outer housing such that when the inner housing is lifted away from the base of the outer housing, the cement drops out of the inner housing and remains in the mixing chamber.

These features are novel and they cannot be derived in an obvious manner from the cited documents.

Moreover, such an apparatus is industrially applicable such that all the requirements of Art. 33(2)-(4) PCT are met.

- 2. The dependent claims 2-9 define particular embodiments of the invention according to claim 1. Thus, these claims also meet the requirements of Art. 33(2)-(4) PCT.
- The arguments set out above under item 1. apply to the method defined in claim 10 mutatis mutandis.
- The independent claims 1 and 10 should have been worded in the two-part form 4. incorporating in their pre-characterising portion the features known from the prior art mentioned in the description (Rule 6.3 (b)).
- 5. Reference signs should have been used throughout the claims (Rule 6.2 b)).



(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference		of Transmittal of International Search Report						
53.70681/001	ACTION (Form PC1/ISA/2	(20) as well as, where applicable, item 5 below.						
International application No.	International filing date (day/month/year)	(Earliest) Priority Date (day/month/year)						
PCT/EP 00/07204	26/07/2000	27/07/1999						
Applicant								
SUMMIT MEDICAL LTD.								
This International Search Report has bee according to Article 18. A copy is being tra	n prepared by this International Searching Auth	nority and is transmitted to the applicant						
	_							
This International Search Report consists It is also accompanied by	of a total of sheets. a copy of each prior art document cited in this	report.						
Basis of the report	-,							
a. With regard to the language, the	international search was carried out on the bases otherwise indicated under this item.	sis of the international application in the						
the international search w Authority (Rule 23.1(b)).	ras carried out on the basis of a translation of t	he international application furnished to this						
was carried out on the basis of the	e sequence listing:	sternational application, the international search						
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the statement that the sub	osequently furnished written sequence listing d is filed has been furnished.	oes not go beyond the disclosure in the						
the statement that the info furnished	ormation recorded in computer readable form is	s identical to the written sequence listing has been						
2. Certain claims were fou	nd unsearchable (See Box I).							
3. Unity of invention is lac	king (see Box II).							
4. With regard to the title,								
X the text is approved as su	bmitted by the applicant.							
the text has been established by this Authority to read as follows:								
5. With regard to the abstract,								
the text is approved as submitted by the applicant. the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.								
6. The figure of the drawings to be pub		1						
X as suggested by the appli		None of the figures.						
because the applicant fail	ed to suggest a figure.	_						
because this figure better	characterizes the invention.							

International application No.

Box III TEXT OF THE ABSTRACT (Continuation of item 5 of the first sheet)

ement (4) can allefining the mixicement (4) prior mixing, in such a 1), for mixing.	ng chamber (1) to mixing. The	and an inner inner inner	housing (2) con (2) is removab	taining the le, prior to	er
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International Application No EP 00/07204

A. CLASSIFICATION OF SUBJECT MATTER IPC 7 A61F2/46 B01F13/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

 $\label{lem:minimum} \begin{tabular}{ll} \begin{tabular}{ll} Minimum documentation searched (classification system followed by classification symbols) \\ IPC 7 & A61F \end{tabular}$

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUM	C. DOCUMENTS CONSIDERED TO BE RELEVANT							
Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.						
Υ	EP 0 397 589 A (WOLFF & KAABER) 14 November 1990 (1990-11-14)	1,5,10						
Α	the whole document	2,7						
Υ	WO 87 05492 A (DRAENERT)	1,5,10						
Α	24 September 1987 (1987-09-24) the whole document	7 .						
A	US 4 015 945 A (FRANKEL) 5 April 1977 (1977-04-05) the whole document	1,8-10						
A	EP 0 178 658 A (MIT AB) 23 April 1986 (1986-04-23) the whole document	3,4,7,8						
	-/							

Further documents are listed in the continuation of box C.	X Patent family members are listed in annex.
Special categories of cited documents: 'A' document defining the general state of the art which is not considered to be of particular relevance 'E' earlier document but published on or after the international filling date 'L' document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) 'O' document referring to an oral disclosure, use, exhibition or other means 'P' document published prior to the international filling date but later than the priority date claimed	 *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art. *&* document member of the same patent family
Date of the actual completion of the international search 12 January 2001	Date of mailing of the international search report 18/01/2001
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Authorized officer Klein, C

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International Application No EP 00/07204

C.(Continu	ation) DOCUMENTS CONSIDER TO BE RELEVANT	
Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 95 22402 A (SUMMIT MEDICAL) 24 August 1995 (1995-08-24) cited in the application the whole document	7
А	WO 97 18031 A (CEMVAC SYSTEM) 22 May 1997 (1997-05-22) the whole document	7,9
A	US 4 185 072 A (PUDERBAUGH) 22 January 1980 (1980-01-22) the whole document	8,9
A	DE 36 40 279 A (MIT AB) 25 June 1987 (1987-06-25)	
Α	WO 93 10892 A (SUMMIT MEDICAL) 10 June 1993 (1993-06-10) cited in the application	

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EP 00/07204 Patent document Publication Patent family Publication cited in search report member(s) date date 14-11-1990 EP 397589 Α AT 101811 T 15-03-1994 627324 B ΑU 20-08-1992 AU 5739690 A 29-11-1990 BR 9007367 A 03-03-1992 2064215 CA 13-11-1990 DE 69006771 31-03-1994 DF 69006771 23-06-1994 Т WO 9013355 A 15-11-1990 DK 397589 T 27-06-1994 ES 2049959 T 01-05-1994 HU 208927 B 28-02-1994 IL 94311 31-07-1994 24-12-1992 JP 4507366 T KR 9501384 B 18-02-1995 NO 914408 A 11-11-1991 NZ 233584 A 26-05-1992 PT 94012 A 28-02-1992 US 5114240 A 19-05-1992 WO 8705492 Α DE 24-09-1987 3609672 A 24-09-1987 AΤ 65689 T 15-08-1991 AT 89993 T 15-06-1993 AT 180656 T 15-06-1999 DE 3752279 D 08-07-1999 DE 3771820 D 05-09-1991 DE 3786049 D 08-07-1993 WO 8705491 A 24-09-1987 06-04-1988 EP 0262185 A EP 0261182 A 30-03-1988 ΕP 0493363 A 01-07-1992 JP 7075613 B 16-08-1995 JP 63502882 T 27-10-1988 JP 2537530 B 25-09-1996 JP 63502883 Τ 27-10-1988 US 4966601 A 30-10-1990 US 5015101 A 14-05-1991 US 4015945 CA Α 05-04-1977 1045113 A 26-12-1978 EP 178658 Α 23-04-1986 SE 450545 B 06-07-1987 AT 88077 T 15-04-1993 AΤ 148331 T 15-02-1997 DE 3587262 A 19-05-1993 DE 3587262 T 25-11-1993 DE 3588140 D 13-03-1997 DE 3588140 T 21-08-1997 EP 0528447 A 24-02-1993 JP 1841991 C 12-05-1994 JP 5052222 В 04-08-1993 JP 61098261 16-05-1986 SE 8405232 A 20-04-1986 US 4721390 A 26-01-1988 WO 9522402 26-06-1997 Α 24-08-1995 ΑU 679335 B AU 1713195 A 04-09-1995 CA 2183660 A 24-08-1995 DE 69505356 D 19-11-1998 06-05-1999 DE 69505356 T

International Application No

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	Internationa	nternational Application No					
	EP	00/07204					
amily		Publication					

	Patent document ed in search report		Publication date		Patent family member(s)	Publication date
WC	9522402	Α		EP ES GB JP	0744991 A 2123958 T 2301045 A,B 9511438 T	18-11-1997
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(19) World Intellectual Property Organization International Bureau





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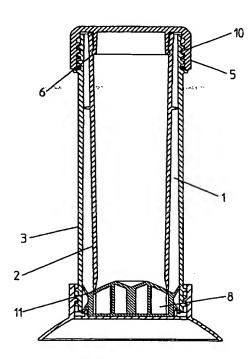
- (81) Designated States (national): AE, AG, AL, AM, AT, AT (utility model), AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, CZ (utility model), DE, DE (utility model), DK, DK (utility model), DM, DZ, EE, EE (utility model), ES, FI, FI (utility model), GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KR (utility model), KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SK (utility model), SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.
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Published:

 Without international search report and to be republished upon receipt of that report.

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: ORTHOPAEDIC BONE CEMENT MIXING CONTAINER



(57) Abstract: The invention discloses a pre-filled orthopaedic cement container in which the cement can also be mixed. The container comprises an outer housing defining the mixing chamber and an inner housing containing the cement prior to mixing. The inner housing is removable, prior to mixing, in such a way that the cement powder remains in the mixing chamber, for mixing.

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Orthopaedic Bone Cement Mixing Container

This invention relates to a container in which orthopaedic bone cement is mixed.

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Orthopaedic bone cement is used throughout the world to secure hip, knee and other metallic protheses in an appropriate anatomical position.

Many different systems are available for mixing orthopaedic bone cement and the type of apparatus selected will depend on the personal preferences of the doctor or nurse mixing the cement, as well as the amount of cement being mixed and the type of materials being used.

Essentially, orthopaedic cement is made up of a powder component, e. g. polymethylmethacrylate powder, and a monomer, eg. g. methylmethacrylate monomer liquid, generally provided in an ampoule which is broken and added to the powder. The two components are then thoroughly mixed to provide a malleable cement which can be manipulated and applied to the appropriate bone parts, during surgery.

In order to avoid the cement becoming brittle, it is essential that the two components are very thoroughly mixed together and no 'dry' or 'dead' spots remain. Furthermore, as most cements set fairly quickly, it is important that the mixing can be quickly and easily carried out. This is, also, of course important as surgery should be carried out as quickly as possible for the comfort and safety of the patient.

Originally, the cement components were mixed, by hand, using a bowl and spatula. A theatre nurse would mix the appropriate quantities of the two components in the bowl and the physician would then take some of the mixed cement and mould it to the required shape, before inserting it into a preformed cavity or applying it to a resected bony surface where the prothesis is to be

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positioned. Cement may either be applied by hand or may be put into a syringe and applied thereby.

- 2 -

Although mixing in this way is straightforward and convenient, it can have drawbacks.

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Firstly, free methylmethacrylate fumes are emitted from the mixture. It is desirable to remove these fumes, or prevent them from escaping into the atmosphere, since they have an unpleasant odour and may be harmful to operating room and personnel. The fumes are known to cause nausea and giddiness and are generally objectionable, particularly to the nurses who actually carry out the mixing.

Secondly, a very high mixing efficiency is required to produce a homogenous cement material During the mixing process, air is naturally introduced into the mixture since air is inherently existent within the powder and also in and around the mixing vessel. Air bubbles are also produced by the 'boiling off' of monomer which occurs during the mixing process. The introduction of air produces a weak cement and, since the joint must usually support a heavy load, it is important to reduce the amount of air in the mixture as much as possible in order to improve the mechanical strength of the cement material.

Furthermore, this mixing process can be slow and result in the cement beginning to dry out before it has been used and can require the patient to be on the operating table longer than desirable. Where particularly viscous cements are used, mixing in this way can also be rather tiring for the theatre nurse and can, in some cases, lead to muscle fatigue and strain.

A variety of systems is now available to simplify and improve the mixing of bone cement and to overcome the problems mentioned above. Many of these include the application of a vacuum to a sealed mixing chamber which removes air from the mixture and avoids weak spots. This results in a greatly improved cement.

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One such mixing device is the bowl mixer forming the subject of European Patent No. 0616552. This system is preferred by many users as it is small and convenient to use and the mixing action is similar to that carried out in the above described manual bowl mixing technique and is one with which nurses are generally familiar.

Another mixing system is described in European Patent No. 0744991. In this arrangement, the cement is mixed in a cylindrical mixing chamber. The mixing mechanism comprises paddles rotatably mounted within the chamber. The paddles are rotated around the chamber by means of a 'barley twist' mechanism so that the user merely has to push the handle up and down, to cause rotation of the paddle. Furthermore, once the cement is mixed, this system can be converted into a syringe type dispenser by addition of a nozzle and plunger. There is thus no need to remove the mixed cement from the mixing chamber and transfer it to a dispenser.

Other similar mixing arrangements are known.

In all of these systems, the cement components need to be put into the mixing chamber. Generally, the nurse is provided with the cement powder, in a bag, and monomer ampoule. These are opened by the nurse, manually, and are introduced into the mixing chamber or bowl by means of funnels.

One problem is that when cutting open the cement powder bag and inserting the powder via the funnel, there is a certain degree of wastage due to spillage and cement clinging to the funnel. Furthermore, the opening and pouring of the cement powder caused a powder cloud which, within the regulated confines of the operating theatre, is unpleasant and may even have adverse effects on the theatre personnel.

These problems become more acute when time is very short and the mixing must be done extremely quickly, or with inexperienced theatre personnel.

One solution which has been considered is to

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provide a pre-filled mixing apparatus, wherein the disposable mixer, for example a bowl mixer or syringe mixer as described above, is supplied already containing the cement powder in the mixing chamber. This generally makes things much easier for the theatre nurse when needing to mix the cement quickly during an operation.

However, tests have shown that if the cement powder is housed within the mixing chamber or bowl and contained therein by means of a cap, the powder moves about, particularly during transportation, and covers the entire internal surface area of the mixing chamber and the lid. When the mixing is carried out, with the introduction of the monomer, unmixed powder remains at the top of the mixing vessel due to the monomer not wetting all of the walled surface, and the mixing paddle not reaching the very fine layer of powder on the walls and at the top of the chamber. Thus, powder is wasted and 'dry' spots occur, resulting in brittle cement which can have adverse consequences.

The aim of the present invention is to provide a pre-filled orthopaedic cement mixing apparatus in which the above mentioned problems are overcome.

According to one aspect of the present invention, there is provided an apparatus for containing and mixing orthopaedic cement, the apparatus containing an outer housing defining a mixing chamber and an inner housing containing the cement prior to mixing, wherein the inner housing is removable from the outer housing such that the cement remains in the mixing chamber.

In accordance with another aspect of the invention, there is provided a method of providing and mixing of orthopaedic cement comprising sealing said cement in an inner housing; disposing said inner housing within an outer housing which defines a mixing chamber; removing the inner housing, leaving the cement in the mixing chamber for mixing.

The present invention may be incorporated into any

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known cement mixing arrangements including the bowl mixer and syringe mixer described above. It may also be incorporated in mixing bowls where the mixing is carried out simply using a spatula etc.

The inner housing may be removable from the outer housing in any way, for example it may be in the form of a bag which is merely lifted out by the user, which opens on removal to drop the cement powder into the mixing chamber. In the most preferred embodiment, however, the inner housing is attached to or formed integrally with a lid provided on the container. The inner housing and the lid may, for example, be attached to each other by a snap fit arrangement or, indeed, by any other means of attachment. Thus, when the cement is to be mixed, the lid is removed by the user and as the lid is removed, it takes with it the inner housing.

To provide a secure container during transportation etc., the lid is preferably attached to the outer housing by means of a screw thread. Seals may also be provided.

The inner housing may be made of any materials suitable for containing the cement powder. Preferably, the material of which the inner housing is made is less rigid than that of the outer housing. This allows the inner housing to be compressed against the outer housing to provide a good seal at the open end of the inner housing.

It is important that, prior to removal of the inner housing, the cement is securely contained within the housing and, therefore, the 'open' end of the inner housing should form a seal with the outer housing or should be closed after filling.

Thus, in one embodiment, not shown, the inner housing has an open end into which the cement is inserted. This open end is then closed by any suitable means and the inner housing is placed within the outer housing in such a manner that when the inner housing is

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removed from the outer housing, the inner housing is opened or ruptured allowing the cement to fall out into the inner housing.

In the most preferred arrangement, the inner housing, at the open end, is provided with a feather seal edge which provides a seal against the base or lower part of the outer housing.

Preferred embodiments of the invention will now be described, by way of example only, with reference to the accompanying drawings.

Fig. 1 shows a cross-section of a mixing system according to the present invention.

Figs. 2A-2D show the different stages of inserting and mixing the cement using the apparatus shown in Fig. 1.

Fig. 3 shows an alternative embodiment of the present invention.

The embodiment shown in Fig. 1 uses a mixing system such as described in EP 0744991. This comprises a cylindrical mixing chamber, in which is arranged a mixing paddle (not shown), rotated by means of a handle connected thereto by a 'barley twist' rod and gear mechanism. The paddle is rotated around the mixing chamber by a pushing and pulling action on the handle. Vacuum is applied to the chamber during the mixing. Once the cement is mixed, the cap and mixing mechanism are removed and replaced by a nozzle. A plunger is applied to the other end of the mixing chamber and is pushed through the chamber, by means of, e. g., a mastic-type gun to eject the mixed cement through the nozzle.

This mixing system is modified by the present invention and is provided as a pre-filled system.

Thus, the cement is provided in an inner housing 2 which is located in the outer, mixing chamber housing 3.

The inner housing, containing the cement 4, is attached to the cap 5 of the mixing chamber by a snap

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fit arrangement 6. This creates a seal through which the cement powder cannot pass.

Fig. 2A shows how the cement is inserted into the inner housing, via the open end 7 of the housing.

The outer housing 3 incorporating the piston and base 8 is then fitted over the cement containing inner housing as shown in Fig. 2D.

Guide lips 9 may be provided on the outer surface of the inner housing to assist in the correct positioning of the outer housing relative to the inner housing.

The outer housing is then secured to the cap, by means of a screw thread 10, as shown in Fig. 2C. The open end of the inner housing, containing the cement, is provided with a seal 11, preferably a feather seal, which fully seals to the piston part of the outer housing to secure the cement powder within the inner housing. This results in a fully sealed packaged container, containing the cement powder within the inner housing, ready for use. The whole device is then packaged and sterilised for use.

A breather pad (not shown) may be provided on the cap so as to allow gas circulation to the cement.

As shown in Fig. 2D, when the cement is to be mixed, the user unscrews the cap 5 from the outer housing 2and lifts away the cap and the inner housing 3 connected thereto. As the inner housing is lifted away from the base of the outer housing, the cement powder 4 drops out of the inner housing into the mixing chamber 1. The cap and inner housing are then discarded and the standard mixing procedure for this type of mixing arrangement is carried out.

A similar procedure is used in relation to other mixing arrangements such as the bowl mixer 12 shown in Fig. 3. This may be a bowl as described in EP 0616552. The principle is essentially the same. An inner housing 3', containing the cement powder 4', is attached to the

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lid 5' of the bowl at one end and is sealed 11' to the base of the bowl or the sides of the bowl near its base by means of e. g. a feather seal. In use, the lid 5' and attached inner housing 3' are removed, such that the cement powder 4' drops out of the inner housing into the mixing chamber 1' and mixing is carried out in the usual way.

It is preferable that the inner housing is made of a material which is less rigid than the outer housing. This allows the feather seal edge of the inner housing to be compressed unto the outer housing to provide a secure seal for the cement powder.

In the preferred syringe type arrangement, the inner housing is designed to hold up to 80g of cement powder, i. e. a double mix of cement. In the case of the bowl mixer, preferably, the inner housing can hold up to 120g, i. e. a triple mix of cement.

Because the cement powder is contained within the inner housing until it is to be mixed, and is then dropped out of the housing only into the bottom of the mixing chamber, no cement clings to the upper outer walls of the mixing chamber and so practically all of the cement can be thoroughly mixed, producing a high quality mixed orthopaedic cement.

CLAIMS

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- 1. An apparatus for containing and mixing orthopaedic cement, the apparatus containing an outer housing defining a mixing chamber and an inner housing containing the cement prior to mixing, wherein the inner housing is removable from the outer housing such that the cement remains in the mixing chamber.
- 2. An apparatus as claimed in claim 1 wherein the outer housing is provided with a cap and wherein the inner housing is attached to said cap such that the cap and inner housing can be removed from the outer housing together.
- 3. An apparatus as claimed in claim 2 wherein the cap is attached to the outer housing by means of a screw thread.
- 4. An apparatus as claimed in claim 2 or 3wherein the inner housing is attached to the cap by means of a snap fit arrangement.
 - 5. An apparatus as claimed in any preceding claim, wherein said inner housing is provided with a feather tip seal for sealing against said outer housing.
 - 6. An apparatus as claimed in any preceding claim wherein said inner housing is less rigid than said outer housing.

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- 7. An apparatus as claimed in any preceding claim wherein said outer housing is in the form of a cylindrical mixing chamber adapted to be provided with a mixing mechanism comprising a blade arrangement rotatable around said chamber.
 - 8. An apparatus as claimed in any preceding claim

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wherein said outer housing is in the form of a bowl shaped mixing chamber adapted to be provided with a mixing mechanism comprising a blade arrangement rotatable around said chamber.

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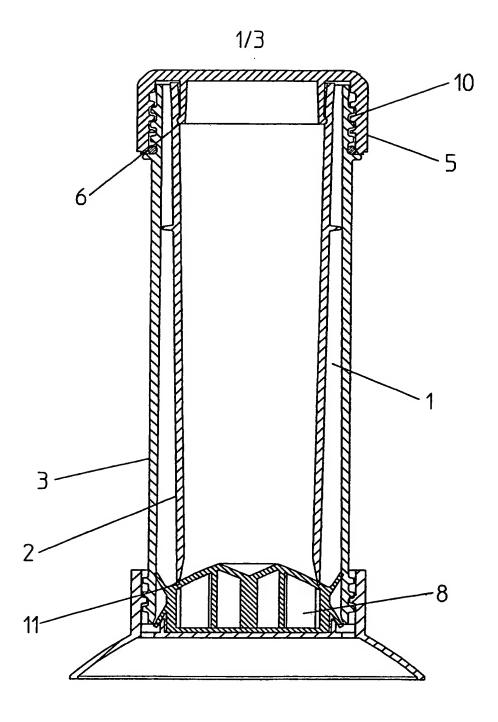
9. An apparatus as claimed in any preceding claim, further comprising means allowing gas to circulate around the cement contained in the inner housing.

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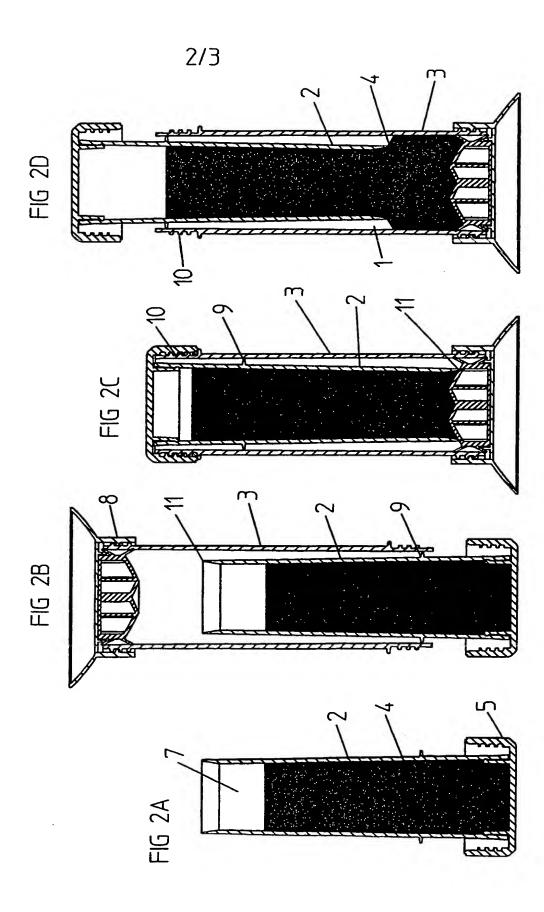
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10. A method of providing and mixing of orthopaedic cement comprising sealing said cement in an inner housing; disposing said inner housing within an outer housing which defines a mixing chamber; removing the inner housing, leaving the cement in the mixing chamber for mixing.

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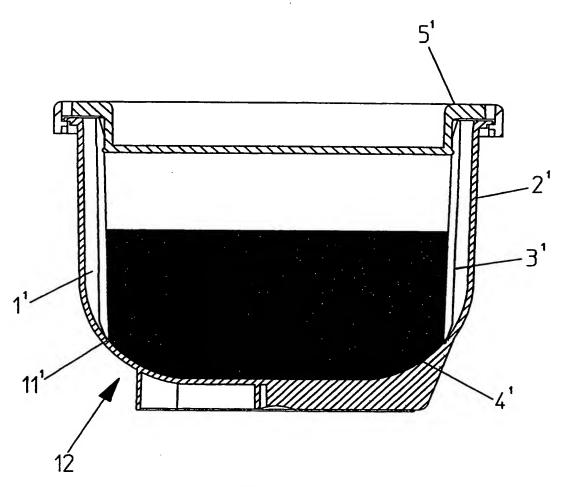


FIG 3

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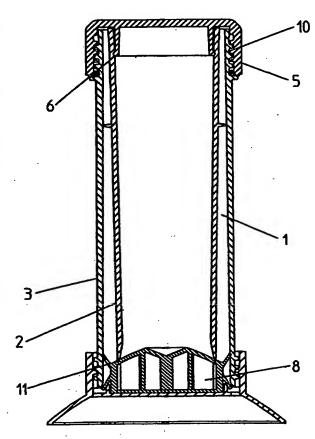
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[Continued on next page]

(54) Title: ORTHOPAEDIC BONE CEMENT MIXING CONTAINER



(57) Abstract: The invention discloses a pre-filled orthopaedic cement container in which the cement (4) can also be mixed. The container comprises an outer housing (3) defining the mixing chamber (1) and an inner housing (2) containing the cement (4) prior to mixing. The inner housing (2) is removable, prior to mixing, in such a way that the cement powder (4) remains in the mixing chamber (1), for mixing.



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SE, SG, SI, SK, SK (utility model), SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

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According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols) IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

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12 January 2001	18/01/2001
Name and mailing address of the ISA	Authorized officer
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Further documents are listed in the continuation of box C.

Patent family members are listed in annex.



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